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Steven Johnson, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for Sulfanilic acids

Dear Administrator Johnson:

The following comments on the Syngenta Crop Protection, Inc. (Syngenta) test plan for 3-methyl benzonitrile are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Syngenta submitted its test plan in December 2005 for the chemical 3-methyl benzonitrile (MTN) (CAS RN 620-22-4). According to the test plan, MTN is a chemical intermediate, used in the production of isophthalonitrile (IPN) and completely consumed in the final production of a FIFRA-regulated fungicide, Chlorothalonil. Syngenta has reviewed processes and available data for MTN, and concluded that no additional testing is necessary, as MTN is created and consumed in a site-limited, intermediate, closed-system process. Available data on MTN include physico-chemical properties and mammalian acute oral, IP, and inhalation data. Although Syngenta indicates that the available mammalian acute toxicity data is inadequate to meet SIDS guidelines, given the entirely closed production and use of MTN, and personal protection and accidental spill procedures already in place, Syngenta surmises that no ecotoxicity or mammalian toxicity data should be collected.

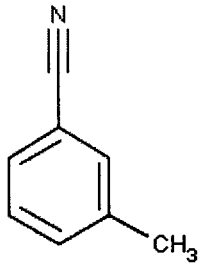
We support this thoughtful toxicology approach. At the same time, we would also like to suggest some strategies that could help fortify the information contained in this test plan, while still avoiding additional animal testing.

First, though it appears that Syngenta did a literature search, additional toxicity information for MTN was found in the TOXLINE database. This data is primarily Ames assay data, but we found two additional references with acute toxicity data that may be more valid than the data that Syngenta lists in the Robust Summaries. The references (1-2) list mouse IP and oral LD50 values of 1000 mg/kg and >300 mg/kg, respectively. While the reliability of these studies cannot be assessed at this time, perhaps Syngenta can add them to the Robust Summaries to supplement the

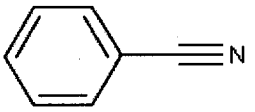
data already listed. The Ames assay data (3) lists 20 assays with a variety of parameters, and all were negative. These data provide a picture of the genetic toxicity profile of MTN and, considering the closed-system intermediate status of MTN, this profile is quite adequate.

Syngenta could also consider using ecotoxicity data from a structurally-similar chemical, benzonitrile (CAS RN 100-47-0). Benzonitrile differs from MTN only by the absence of the *meta* methyl group on the benzene ring (Figure 1), and the two chemicals appear to have similar physico-chemical properties, according to TOXLINE data. Furthermore, several ecotoxicity assays on protozoa, algae, fathead minnow, bluegill, and guppy species are available for benzonitrile. This reference (4) likely contains sufficient information to characterize the ecotoxicity data profile for MTN, especially since MTN is consumed entirely in the creation of Chlorothalonil and is not transported off-site. This approach could be further fortified by running ECOSAR simulations for MTN.

Figure 1



3-methyl benzonitrile



benzonitrile

This test plan is an example of the thoughtful toxicology that is needed to be consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research

References Cited

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